REMARKS

Claims 1-20 were pending in the application upon the issuance of the Office Action dated April 18, 2006. In the present amendment, claims 1-10 have been cancelled without prejudice as being drawn to non-elected subject matter; claims 11-15 and 17 have been amended, and new claims 27 -36 have been added. In addition, the specification and abstract have been amended to correct minor typographical errors. Support for these amendments may be found throughout the specification and claims as originally filed. *Accordingly, no new matter has been added.*

Upon entry of the foregoing amendments, claims 11-20 and 27-36 will be pending and under examination. The claim cancellations requested herein should in no way be construed as acquiescence to any of the rejections and have been made solely to expedite prosecution of the application. Applicants reserve the right to pursue the claims as originally filed and/or prior to amendment herein in this or a separate application(s).

Election/Restriction

The Office Action, on page 2, sets forth a requirement for restriction to one of the following groups under 35 U.S.C. §121:

Group I: Claims 1-10, drawn to a ribosome-inactivating polypeptide, classified in class 435, subclass 199.

Group II: Claims 11-20, drawn to a polynucleotide encoding a ribosome-inactivating polypeptide, vector, host cell, and recombinant method of making the encoded protein, classified in class 536, subclass 23.2.

Applicants hereby affirm the election of Group II (claims 11-20), without traverse.

Drawings-Objections

Figure 3 was objected to for disclosing sequence that are not identified by a sequence identifier number (SEQ ID NO:) as required by 37 CFR §1.821(d). The specification has now been amended to include the required sequence identifier numbers in the figure legend for Figure 3. Accordingly, withdrawal of this objection is respectfully requested.

Abstract-Objection

The Abstract was objected to on the ground that the first phrase is a run-on sentence. Applicants submit herewith an amended Abstract and request withdrawal of this objection.

Specification-Objections

The specification was objected to for not accurately reflecting the issuance of the parent application. Accordingly, Applicants have amended the specification to contain the requested information, and request withdrawal of this objection.

The specification was further objected to on the ground that the results presented in Table 2 have no units. Applicants respectfully submit that units for the IC_{50} values presented in Table 2 are not required to establish the patentability of the claimed invention. However, Applicants in view of the units for the IC_{50} values for free RIP presented in Tables 1 and 3-5, one skilled in the art would understand that the values presented in Table 2 are expressed in ng/ml. Accordingly, Table 2 has been amended include this value and withdrawal of this objection is requested.

Claims-Objections

The claims were objected to on a number of grounds including improper antecedent basis and/or for being dependent from non-elected claims. Applicants submit that these objections have been rendered moot by the foregoing amendments to the claims.

Claim Rejections – 35 USC § 112-Second Paragraph

Claims 12-14 were rejected as indefinite on the ground that they are improperly dependent on Claim 10. This rejection has been rendered moot by the amendment of the claims to depend from claim 11.

Claim 11 was rejected on the ground that the phrases, "comprising a sequence of at least 15, especially at least 24 nucleotides" and "or part thereof", and the term "equivalent" are indefinite. This rejection has been rendered moot by the amendment of the claim to remove this phrase.

Claim 13 was rejected on the ground that it is unclear whether the phrase "oligonucleotide sequence" is meant to be "oligonucleotide or polynucleotide sequence." This

rejection has been rendered moot by the amendment of claims 11 and 12 to remove the term "oligonucleotide."

Claims 15 and 17 were rejected on the ground that it is unclear whether the term "bouganin" refers to a specific protein purified in Example 1, or a genus of proteins having the recited characteristics. Claims 15 and 17 have been amended to replace the term "bouganin" with the specific characteristics of the protein produced by the claimed methods. Accordingly, withdrawal of this rejection is requested.

Claim 19 has been rejected on the ground that the terms "large" and "small" are relative terms that render the claims indefinite. Applicants submit that this rejection has been rendered moot by the amendment of this claim to remove these terms.

Claim Rejections – 35 USC §112 - First Paragraph

Enablement

Claims 11-20 were rejected on the ground that "the specification does not reasonably provide enablement for any polynucleotide encoding any RIP of ~26kD, pI 9.0, and having at the N-terminus, a sequence having at least 50% homology to SEQ ID NO:1 or any recombinant method of making any bouganin." (Office Action at pages 7-8)

The test for enablement is whether one skilled in the art could make or use the claimed invention from the disclosure in the patent application with information known in the art without undue experimentation. (*See*, for example, *United States v. Telectronics, Inc.*, 8 U.S.P.Q.2d 1217, 1222 (Fed. Cir. 1988)). Accordingly, Applicants respectfully traverse this rejection with respect to the pending claims.

The pending claims specify that the encoded ribosome-inactivating protein, biologically active fragments and toxin-ligand conjugates have specific structural (*i.e.,* molecular weight, pI and/or sequence) and functional (*i.e.,* ribosome inactivating activity) characteristics. The instant specification provides amino acid sequences of a novel type-1 ribosome-inactivating protein (RIP), bouganin, and provides an alignment of the N-terminal amino acid sequence set forth in SEQ ID No. 1 with 15 other known type-1 RIPs. Examples 1-8 of the specification also teach how to make toxin-ligand conjugates containing this protein, how to make and express polynucleotides encoding RIP proteins and conjugates and, further, how to test the expression

products of the polynucleotides for ribosome-inactivating activity. Thus, Applicants respectfully submit that, given the information provided and the high level of skill in the art, only routine experimentation would be required to make polynucleotides within the scope of the claimed invention and to test whether the encoded protein or fragment has ribosome-inactivating activity.

Accordingly, Applicants respectfully request reconsideration and withdrawal of this rejection.

Written Description

Claims 11-20 were further rejected on the ground that specification lacks sufficient written description to establish that Applicants had possession of the genus of nucleic acid molecules encoding any RIP of ~26kD, pI 9.0, and an N-terminal sequence having at least 50% homology to SEQ ID NO:1; to vectors and host cells comprising the genus of nucleic acid molecules, or any recombinant method of making any RPI molecule.

Applicants traverse this rejection. The correct standard for written description does not require a specification disclose each and every embodiment encompassed by a claim, but that the specification provides sufficient disclosure for one skilled in the art at the time of the invention to make and use the embodiments encompassed by the claims without undue experimentation. For example, as the Federal Circuit explained in *Lizardtech v. Earth Resource Mapping, Inc.* 424 F. 3d 1336 (Fed. Cir. 2005)

> [a] claim will not be invalidated on section 112 grounds simply because the embodiments of the specification do not contain examples explicitly covering the full scope of the claim language. *See* Union Oil Co. v. Atl. Richfield Co., 208 F.3d 989, 997 (Fed. Cir. 2000). That is because the patent specification is written for a person of skill in the art, and such a person comes to the patent with the knowledge of what has come before. In re GPAC Inc., 57 F.3d 1573, 1579 (Fed. Cir. 1995). Placed in that context, it is unnecessary to spell out every detail of the invention in the specification; only enough must be included to convince a person of skill in the art that the inventor possessed the invention and to enable such a person to make and use the invention without undue experimentation

As stated above, the pending claims now specify that the encoded ribosome-inactivating protein, biologically active fragments and toxin-ligand conjugates have specific structural (*i.e.*,

molecular weight, pI and/or sequence) and functional (*i.e.*, ribosome inactivating activity) characteristics. Moreover, methods for generating and expressing the claimed polynucleotides, as well as testing the encoded polypeptides for ribosome-inactivating activity, are described in the specification and would be a matter of routine given the level of skill in the art.

Accordingly, Applicants respectfully submit that the specification contains sufficient written description to establish that Applicants were in possession of the subject matter of the presently amended claims, and reconsideration and withdrawal of this rejection is respectfully requested.

CONCLUSION

In view of the remarks set forth above, it is respectfully submitted that this application is in condition for allowance. If there are any remaining issues or the Examiner believes that a telephone conversation with Applicants' Attorney would be helpful in expediting prosecution of this application, the Examiner is invited to call the undersigned at (617) 227-7400.

Applicants believe that no fee is due with the filing of this paper, however, should any fee be due, the Director is authorized to charge it to the Deposit Account No. 12-0080, under PNJ-005CN, from which the undersigned is authorized to draw.

Dated: July 18, 2006

Respectfully submitted,

By _____

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